PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		**Docket No.:**	**2780-183**
Applicant:	**Henry Kopf III**	**Examiner:**	**Savage, Matthew O.**
Application No.:	**09/818,823**	**Art Unit:**	**1723**
Date Filed:	**March 27, 2001**	**Confirmation No.:**	**9987**
Title:	**INTEGRAL GASKETED FILTRATION CASSETTE ARTICLE AND METHOD OF MAKING THE SAME**	**Customer No.:**	**23448**

EXPRESS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Arlington, Virginia 22313-1450, and Express Mailed under the provisions of 37 CFR 1.10.

L. Stephen Lockett

L. Stephen Lockett

July 28, 2004

Date

EO 00232846 5 US

Express Mail Label Number

DECLARATION OF MICHAEL M. MEAGHER SUBMITTED UNDER 37 C.F.R. §1.132 IN U.S. PATENT APPLICATION NO. 09/818,823

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, MICHAEL M. MEAGHER, hereby declare:

1. THAT I am a Professor at the University of Nebraska-Lincoln and am the founder and Director of the Biological Process Development Facility ("the BPDF") at the University of Nebraska-Lincoln, which is recognized as one of the premier academic Bioprocessing Facilities/Centers in the United States.

2. THAT I received my B.S. in Engineering Science from Colorado State University in 1981 and my M.S. and Ph.D. in Chemical Engineering from Iowa State University in 1984 and 1987, respectively.

3. THAT I have published no less than 43 peer reviewed research papers, have prepared a chapter for the book *Membrane Separations in Biotechnology* (Ed. W. Wang, 2nd ed., pp 189-204, 2001), have prepared a chapter for the book *Methods in Molecular Biology V. 103* (Ed. D.R. Higgins and J.M. Cregg, Humana Press Inc, 1998), and am a listed inventor on U.S. Patent No. 6,699,691 for "Alcohol Oxidase I Regulatory Nucleotide Sequences for Heterologous Gene Expression in Yeast," U.S. Patent No. 6,447,856 for "Hydrothermal Gel Process for Preparation of Silicalite Particles and Process for Preparation of Composite Membranes," U.S. Patent No. 6,423,119 for "Poly(1-trimethylsilyl-1-propyne) Membrane Regeneration Process," U.S. Patent No. 5,981,237 for "Silicalite Membrane and Method for the Selective Recovery and Concentration of Acetone and Butanol from Model ABE Solutions and Fermentation Broths," and U.S. Patent No. 5,775,967 for "Method for Liquefaction of Cereal Grain Starch Substrate and Apparatus Therefore."

4. THAT I have worked in the bioprocessing area for seventeen (17) years and one current focus of my research is the use of cross-flow membrane filtration for the recovery of recombinant proteins from *Pichia pastoris*, whereby cross-flow microfiltration is used as an alternative to centrifugation. The effective centrifugation of the *P.pastoris* fermentation broth has proven to be difficult because of the high cell densities of the *P.pastoris* broth. Towards that end, I have collaborated extensively with Henry Kopf III (the "Inventor") in the understanding and development of a large-scale system to efficiently harvest these high cell density fermentations using cross-flow membrane filters.

5. THAT I have used the integral gasketed filtration cassette that is described and claimed in U.S. Patent Application No. 09/818,823 filed in the United States Patent and Trademark Office on March 27, 2001 in the name of Henry Kopf III, for "INTEGRAL GASKETED FILTRATION CASSETTE ARTICLE AND METHOD OF MAKING THE SAME" (the "Application").

6. THAT the integral gasketed filtration cassette of the Application comprises a cross-flow fluid filtration cassette overcoated by at least one thin gasket layer, wherein said thin gasket layer provides a fluid-tight seal between the filtration cassette and the cassette holder to which the filtration cassette is to be affixed.

7. THAT I have used the integral gasketed filtration cassette of the Application at the Biological Process Development Facility at the University of Nebraska-Lincoln while concentrating recombinant proteins.

8. THAT the integral gasketed filtration cassette of the Application that I have used comprises a 1 ft^2 filtration surface and a 5,000 MW poly(ether) sulfone ("PES") membrane.

9. THAT I have used other filtration cassettes including the Millipore Ultrafiltration Prostak module ("Prostak") and the Millipore Pellicon cassette system ("Pellicon") to concentrate recombinant proteins.

10. THAT the integral gasketed filtration cassette of the Application is superior to the Prostak and the Pellicon. The integral gasketed filtration cassette of the Application makes insertion of the membrane into the cassette holder dramatically easier and provides a more reliable fit against the cassette holder plate.

11. THAT the ease of use is the most substantial advantage of the integral gasketed filtration cassette of the Application. Unlike other commercially available filtration cassettes, such as the Prostak and the Pellicon, the integral gasketed filtration cassette of the Application does not become misaligned during filtration and as such, does not leak. If a filtration problem arose while using the Prostak and the Pellicon,

it was difficult to determine if the filter or the gasket had failed. The integral gasketed filtration cassette of the Application eliminates that problem.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

7/26/2004

Michael M. Meagher